

General

Guideline Title

Guidelines for laparoscopic peritoneal dialysis access surgery.

Bibliographic Source(s)

Haggerty S, Roth S, Walsh D, Stefanidis D, Price R, Fanelli RD, Penner T, Richardson W, SAGES Guidelines Committee. Guidelines for laparoscopic peritoneal dialysis access surgery. Los Angeles (CA): Society of American Gastrointestinal and Endoscopic Surgeons (SAGES); 2014 Jun. 53 p. [234 references]

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Regulatory Alert

FDA Warning/Regulatory Alert

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

• December 14, 2016 – General anesthetic and sedation drugs : The U.S. Food and Drug Administration (FDA) is warning that repeated or lengthy use of general anesthetic and sedation drugs during surgeries or procedures in children younger than 3 years or in pregnant women during their third trimester may affect the development of children's brains. Consistent with animal studies, recent human studies suggest that a single, relatively short exposure to general anesthetic and sedation drugs in infants or toddlers is unlikely to have negative effects on behavior or learning. However, further research is needed to fully characterize how early life anesthetic exposure affects children's brain development.

Recommendations

Major Recommendations

Definitions of the levels of (+, ++, +++, +++++) and the grades of the recommendations (Weak or Strong) are provided at the end of the "Major Recommendations" field.

Patient Selection

- 1. Contraindications for laparoscopic peritoneal dialysis (PD) catheter placement include active abdominal infection and uncorrectable mechanical defects of the abdominal wall. (+++ Evidence, Strong recommendation)
- 2. History of prior abdominal surgery, regardless of how many, is not a contraindication to laparoscopic PD catheter insertion. It is appropriate for surgeons with experience in advanced laparoscopy to attempt lysis of adhesions and catheter placement in these patients. (+++ Evidence, Strong recommendation)
- 3. Patients with abdominal wall hernias should be diagnosed and repaired before or at the same time as PD catheter insertion. A repair should be chosen that minimizes peritoneal dissection and does not place mesh intraperitoneally. (++ Evidence, Weak recommendation)
- 4. Peritoneal dialysis may be initiated in patients with intraabdominal foreign bodies such as after open abdominal aortic aneurysm graft repair, but a four month waiting period is recommended. Very limited data exists regarding peritoneal dialysis in the presence of an adjustable gastric band. (++ Evidence, Weak recommendation)
- 5. Peritoneal dialysis may be safely initiated in patients with ventriculoperitoneal shunts. (++ Evidence, Weak recommendation)
- 6. Gastrostomy tubes can be used in pediatric patients on peritoneal dialysis, though placement by blind percutaneous endoscopic technique (PEG) appears to be associated with higher infection rates compared to open insertion. (++ Evidence, Weak recommendation)
- 7. Laparoscopic PD catheter insertion with carbon dioxide pneumoperitoneum requires general anesthesia. Patients who are high risk to undergo general anesthesia should be considered for a technique of catheter insertion that only requires local anesthesia and sedation, such as open insertion or fluoroscopically guided percutaneous insertion. Laparoscopic insertion using nitrous oxide pneumoperitoneum and local anesthesia is also an option where available. (++ Evidence, Weak recommendation)

Insertion Options

8. For peritoneal access, blind percutaneous, open surgical, peritoneoscopic, fluoroscopically guided percutaneous, and laparoscopic insertion procedures, when performed by experienced operators, are feasible and safe with acceptable outcomes. (+++ Evidence, Strong recommendation)

Advanced Laparoscopic Techniques to Avoid Catheter Dysfunction

- 9. Laparoscopic lysis of adhesions should be incorporated to reduce catheter dysfunction. (+++ Evidence, Strong recommendation)
- 10. Laparoscopic suture fixation of the PD catheter may reduce catheter dysfunction but additional is needed. (++ Evidence, Weak recommendation)
- 11. Rectus sheath tunneling helps prevent migration and may be superior to suture fixation since it does not require added ports and instruments. (++ Evidence, Weak recommendation)
- 12. Omentopexy in adults is a safe adjunct to laparoscopic PD catheter insertion and should be incorporated either routinely or selectively to reduce catheter dysfunction. (+++ Evidence, Weak recommendation)
- 13. Omentectomy should be considered in pediatric patients undergoing peritoneal dialysis catheter placement. (++ Evidence, Weak recommendation)
- 14. The combination of lysis of adhesions, peritoneal tunneling and omentopexy in combination offers the lowest rate of postoperative PD catheter dysfunction and should be a preferred technique in adults. (+++ Evidence, Strong recommendation)

Perioperative Considerations

- 15. Presurgical assessment should include thorough examination for hernias and the catheter exit site should be marked before surgery. (+ Evidence, Weak recommendation)
- 16. A need for preoperative bowel preparation has not been conclusively demonstrated and further is needed before a recommendation can be provided.
- 17. Prophylactic antibiotics should be used prior to laparoscopic insertion of PD catheter. Vancomycin may be superior to first generation cephalosporins in minimizing early peritonitis after PD insertion but local resistance patterns should be also considered when choosing the preoperative antibiotic. (+++ Evidence, Strong recommendation)

Surgical Technique

- 18. Peritoneal access during lap PD insertion should be obtained away from previous scars; surgeons should use the technique they are most comfortable and experienced with. (++ Evidence, Weak recommendation)
- 19. The surgeon should minimize the size and number of ports used and place them in a manner that optimizes visualization of the catheter peritoneal insertion point and the pelvis. (++ Evidence, Weak recommendation)
- 20. When inserting the PD catheter through the abdominal wall, the deep cuff should be placed inside the rectus sheath. (++ Evidence, Strong

- recommendation).
- 21. The superficial PD catheter cuff should be 2 cm from the skin exit site in children and at least 2 cm in adults to prevent future cuff extrusion. (+ Evidence, Weak recommendation)

Postoperative Protocol

- 22. Minimizing dressing changes and handling may be beneficial in the first two postop weeks. (+ Evidence, Weak recommendation)
- 23. Adequate time should be given after surgery for healing before PD is initiated and the current standard is two weeks. A more urgent start should be considered when the benefits outweigh the risks. (++ Evidence, Weak recommendation)

Comparative Studies in Adults

Summary of Outcomes by Surgical Procedure

- 24. Blind percutaneous PD catheter insertion has acceptable malfunction and leak rates compared with open insertion in patients who have never had prior abdominal surgery. The technique may be especially useful in high-risk patients for general anesthesia as it can be performed at the bedside, under local anesthesia by trained nephrologists. However, bowel perforation and bleeding risk should be considered. (+++ Evidence, Weak recommendation)
- 25. Open surgical insertion continues to be a standard to which others are compared. It is safe (low perforation rate) and effective and can be performed under local anesthesia and sedation. It appears to have higher leak and dysfunction rates compared to image guided percutaneous and advanced laparoscopic insertion. (+++ Evidence, Weak recommendation)
- 26. Peritoneoscopic insertion is a technique used worldwide, mostly by "interventional" nephrologists. It has been studied in patients who have had prior surgery, but there is at least a 1% perforation rate. It appears to be comparable to open surgical insertion in experienced hands, but has not been compared to laparoscopic and fluoroscopic guided percutaneous insertion. (++ Evidence, Weak recommendation)
- 27. In patients without prior abdominal surgery, percutaneous fluoroscopic PD catheter insertion results in similar or better complication rates and dysfunction rates compared to open or basic laparoscopic insertion, and avoids general anesthesia. (+++ Evidence, Weak recommendation)
- 28. Basic laparoscopic insertion without using techniques to minimize catheter dysfunction results in similar dysfunction rates as open insertion. (+++ Evidence, Strong recommendation)
- 29. Advanced laparoscopic PD catheter insertion using lysis of adhesions, catheter fixation preferably with long rectus sheath tunnel, and omentopexy performed in combination has the lowest reported rate of catheter dysfunction in adults, even in patients with prior abdominal surgery. (+++ Evidence, Strong recommendation)

Early Postoperative Complications

- 30. Bleeding after PD catheter insertion may occur from inferior epigastric artery injury or lysis of adhesions and should be managed according to standard surgical principles. The insertion point should be at the medial border of the rectus sheath to avoid arterial injury. Coagulation parameters should be assessed and corrected pre-operatively. (+ Evidence, Weak recommendation)
- 31. Dialysate leaks after PD catheter placement may be amenable to treatment, and potentially prevention, with the use of fibrin glue, particularly in the pediatric population. (++ Evidence, Weak recommendation)
- 32. Exit site infection is managed by oral antibiotics. Chronic exit site and cuff infections may be managed by catheter salvage consisting of unroofing the track, shaving the superficial cuff and using a new exit site. (++ Evidence, Weak recommendation)
- 33. Pain during PD is a rare complication that is usually amenable to medical management but occasionally requires repositioning or removal of the catheter. (++ Evidence, Weak recommendation)

PD Catheter Malfunction

- 34. Malfunctioning PD catheters should be evaluated by physical examination and plain radiographs to rule out constipation. If negative, further studies such as catheterography or computed tomography (CT) peritoneography, followed by diagnostic laparoscopy are indicated. (++ Evidence, Weak recommendation)
- 35. Non-operative treatments of malfunctioning PD catheters which have been proven effective include flushing, thrombolytics and fluoroscopic wire manipulation. (++ Evidence, Weak recommendation)
- 36. Patients with malfunctioning peritoneal dialysis catheters not amenable to nonoperative measures should undergo laparoscopy with catheter repositioning, adhesiolysis, omentectomy or omentopexy. Patency should be assured by stripping and flushing. Suture fixation of the catheter to the pelvis or polypropylene sling may be utilized to reduce catheter migration. Surgical techniques for catheter salvage require individualization based upon operative findings. (++++ Evidence, Strong recommendation)

Definitions:

GRADE* System for Rating the Quality of Evidence for Society of American Gastrointestinal Endoscopic Surgeons (SAGES) Guidelines

Quality of Evidence	Definition	Symbol Used
High quality	Further research is very unlikely to alter confidence in the estimate of impact	++++
Moderate quality	Further research is likely to alter confidence in the estimate of impact and may change the estimate	+++
Low quality	Further research is very likely to alter confidence in the estimate of impact and is likely to change the estimate	++
Very low quality	Any estimate of impact is uncertain	+

Grading of Recommendations Assessment, Development and Evaluation (GRADE)* Recommendations Based on the Quality of Evidence for Society of American Gastrointestinal Endoscopic Surgeons (SAGES) Guidelines

Strong: It is very certain that benefit exceeds risk for the option considered.

Weak: Risk and benefit well balanced, patients and providers faced with differing clinical situations likely would make different choices, or benefits available but not certain regarding the option considered.

*Adapted from Guyatt GH, Oxman AD, Vist GE, et al; GRADE Working Group. GRADE: An emerging consensus on rating quality of evidence and strength of recommendations. BMJ 2008; 336:924-6.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Renal failure

Guideline Category

Evaluation

Management

Treatment

Clinical Specialty

Internal Medicine

Nephrology

Radiology

Surgery

Intended Users

Guideline Objective(s)

To provide specific recommendations to assist surgeons who take care of adult and pediatric peritoneal dialysis (PD) patients

Target Population

Patients with renal failure

Interventions and Practices Considered

- 1. Patient selection
 - Consideration of patient history (prior abdominal surgery, intraabdominal foreign bodies, abdominal wall hernias, ventriculoperitoneal shunts)
 - Consideration of contraindications for laparoscopic peritoneal dialysis (PD)
- 2. Insertion options
 - Blind percutaneous
 - Open surgical
 - Peritoneoscopic
 - Fluoroscopically guided percutaneous
 - Laparoscopic
- 3. Advanced laparoscopic techniques to avoid catheter dysfunction (e.g., laparoscopic lysis)
- 4. Perioperative considerations
 - Examination for hernias and determination of catheter exit site
 - Preoperative bowel preparation (not recommended)
 - Prophylactic antibiotics
- 5. Surgical technique
 - Peritoneal access away from previous scars
 - Minimizing size and number of ports
 - Deep cuff placement inside the rectus sheath
 - Superficial PD catheter cuff at least 2 cm from the skin exit site
- 6. Postoperative protocol (adequate healing time and minimal dressing changes)
- 7. Management of postoperative complications (bleeding, leakage, infection, pain)
- 8. Evaluation and management of PD catheter malfunction

Major Outcomes Considered

- Early and late dysfunction requiring catheter removal or surgical repositioning
- Dialysate leak
- Perioperative complications such as bleeding and perforation

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

A systematic literature search was performed on MEDLINE in May 2010 and was updated January 2013. Articles were limited to English language. Additional articles found on the latest search were included in the totals and incorporated into the guideline final draft. The search strategy is detailed in Figure 1 of the original guideline document. The search strategy identified 66 articles on laparoscopic insertion of peritoneal dialysis (PD) catheters. Of these 37 were on salvage and 14 on peritoneoscopic insertion. The abstracts were reviewed by two committee members and divided into the following categories:

- a. Randomized studies, meta-analyses, and systematic reviews
- b. Prospective studies
- c. Retrospective studies
- d. Case reports
- e. Review articles
- f. Clinical practice guidelines

Randomized controlled trials, meta-analyses, and systematic reviews were selected for further review along with prospective and retrospective studies when a higher level of evidence was lacking. For inclusion, prospective and retrospective studies had to report outcomes on at least 30 laparoscopic PD catheter insertions. Studies with smaller samples were considered when additional evidence was lacking. The most recent reviews were also included. All case reports, old reviews, and smaller studies were excluded. Duplicate publications or patient populations were considered only once. Whenever the available evidence from Level I studies was considered to be adequate, lower evidence level studies were not considered.

The reviewers graded the level of evidence and searched the bibliography of each article for additional articles that may have been missed during the original search. Additional relevant articles were obtained and included in the review for grading. A separate search pertaining to pediatric patients was undertaken in 2013. The search strategy is outlined in Figure 2 in the original guideline document. Due to lower case numbers, prospective and retrospective studies in pediatric patients had to report outcomes on at least 15 peritoneal dialysis catheter insertions. Studies with smaller samples were considered when additional evidence was lacking. Forty-five articles relevant to pediatric patients were reviewed by a committee member.

Number of Source Documents

Overall, a total of 170 graded articles relevant to laparoscopic peritoneal dialysis (PD) insertion were included in this review to formulate the recommendations in this guideline.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Grading of Recommendations Assessment, Development and Evaluation (GRADE)* System for Rating the Quality of Evidence for Society of American Gastrointestinal Endoscopic Surgeons (SAGES) Guidelines

Quality of Evidence	Definition	Symbol Used
High quality	Further research is very unlikely to alter confidence in the estimate of impact	++++
Moderate quality	Further research is likely to alter confidence in the estimate of impact and may change the estimate	+++
Low quality	Further research is very likely to alter confidence in the estimate of impact and is likely to change the estimate	++
Very low quality	Any estimate of impact is uncertain	+

^{*}Adapted from: Guyatt GH, Oxman AD, Vist GE, et al; GRADE Working Group. GRADE: An emerging consensus on rating quality of evidence and strength of recommendations. BMJ 2008; 336:924-6.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review

Description of the Methods Used to Analyze the Evidence

Both the quality of the evidence and the strength of the recommendation for each of the guidelines were assessed according to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system. See the "Rating Scheme for the Strength of the Evidence" field.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Both the quality of the evidence and the strength of the recommendation for each of the guidelines were assessed according to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system. See the "Rating Scheme for the Strength of the Recommendations" field.

Rating Scheme for the Strength of the Recommendations

Grading of Recommendations Assessment, Development and Evaluation (GRADE)* Recommendations Based on the Quality of Evidence for Society of American Gastrointestinal Endoscopic Surgeons (SAGES) Guidelines

Strong: It is very certain that benefit exceeds risk for the option considered.

Weak: Risk and benefit well balanced, patients in differing clinical situations would make different choices, or benefits available but not certain

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Cost Analysis

In a study that evaluated open surgery vs. basic laparoscopic, it was concluded that laparoscopic insertion was not cost effective and recommended conventional open surgery for most patients needing primary catheter placement.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

Guidelines are developed under the auspices of the Society of American Gastrointestinal and Endoscopic Surgeons and its various committees, and approved by the Board of Governors. Each clinical practice guideline has been systematically researched, reviewed and revised by the guidelines committee, and reviewed by an appropriate multidisciplinary team.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate use of laparoscopic access surgery for insertion of peritoneal dialysis (PD) catheters and salvage of malfunctioning catheters

Potential Harms

- The primary causes of catheter dysfunction in laparoscopic insertion are compartmentalization from adhesions, catheter tip migration into the upper abdomen, and omental wrapping or entrapment.
- A peritoneoscopic technique does not allow for adhesiolysis, requires specialized equipment and expertise and has a risk of vascular and bowel injury on insertion. Its use has fallen to less than 1% in the United States as of 2012.
- See Tables 1-4 in the original guideline document for complications associated with insertion techniques and laparoscopic salvage of peritoneal dialysis (PD) catheters for adult and pediatric patients.
- There have been reports of suture fixation preventing easy catheter removal as well as being a potential cause of internal hernia or adhesions. It may also impair the natural ability of the catheter to "float" to the largest area of PD fluid.

Contraindications

Contraindications

Absolute Contraindications

The conditions below are considered absolute contraindications to peritoneal dialysis (PD) catheter placement for renal replacement therapy. Novel uses like PD for treatment of edema in the open abdomen patient, or catheter placement for ascites management or intraperitoneal chemotherapy are not discussed and should be considered on a case by case basis.

- 1. Documented loss of peritoneal function such as ultrafiltration failure of the peritoneal membrane
- 2. In the absence of a suitable assistant, impaired physical and mental ability of the patient to safely use the equipment on a daily basis, (severe active psychotic disorder, marked intellectual disability, poor home situation, impaired manual dexterity, and blindness)
- 3. Severe protein malnutrition and or proteinuria >10 g/day
- 4. Active intraabdominal, abdominal wall or skin infection which leads to high incidence of catheter infection by direct contact, such as active Crohn's disease, ulcerative colitis and ischemic colitis. Frequent episodes of diverticulitis are also a contraindication since there may be an increased risk for transmural contamination by enteric organisms

Relative Contraindications

There are certain conditions that are relative contraindications to PD catheter insertion or specifically laparoscopic insertion if there is a very high risk of complications or failure of dialysis to work.

- 1. Decreased capacity of peritoneal cavity
- 2. Lack of integrity of the abdominal wall
- 3. Obesity
- 4. Intraabdominal foreign body
- 5. Ostomy
- 6. Inability to tolerate general anesthesia

See the original guideline document for more information on each relative contraindication.

Qualifying Statements

Qualifying Statements

- Guidelines for clinical practice are intended to indicate preferable approaches to medical problems as established by experts in the field. These recommendations will be based on existing data or a consensus of expert opinion when little or no data are available. Guidelines are applicable to all physicians who address the clinical problem(s) without regard to specialty training or interests, and are intended to indicate the preferable, but not necessarily the only acceptable approaches due to the complexity of the healthcare environment. Guidelines are intended to be flexible. Given the wide range of specifics in any health care problem, the surgeon must always choose the course best suited to the individual patient and the variables in existence at the moment of decision.
- Guidelines are developed under the auspices of the Society of American Gastrointestinal and Endoscopic Surgeons and its various
 committees, and approved by the Board of Governors. Each clinical practice guideline has been systematically researched, reviewed and
 revised by the guidelines committee, and reviewed by an appropriate multidisciplinary team. The recommendations are therefore considered
 valid at the time of its production based on the data available. Each guideline is scheduled for periodic review to allow incorporation of
 pertinent new developments in medical research knowledge, and practice.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

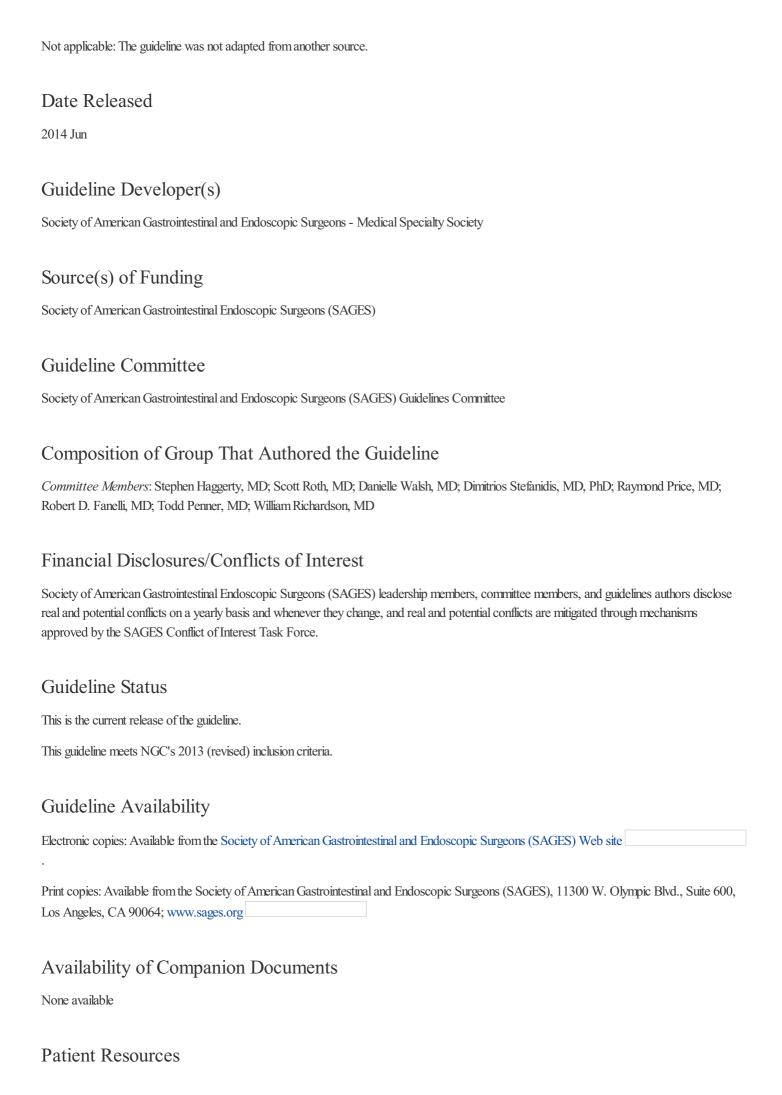
Effectiveness

Safety

Identifying Information and Availability

Bibliographic Source(s)

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NGC Status

This NGC summary was completed by ECRI Institute on August 25, 2014. This summary was updated by ECRI Institute on February 15, 2017 following the U.S. Food and Drug Administration advisory on general anesthetic and sedation drugs.

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